U.L ENVIRONMENTAL PROTECTION AGENCY INTERAGENCY AGREEMENT (Please read instructions on page 3)

I. EFFECTIVE DA 7/1/84

6/30/87

COMPLETION DATE

DW75930893-01-0

4. HAME AND ADDRESS OF EPA ORGANIZATION

U.S. Environmental Protection Agency (EPA) Office of Solid Waste and Emergency Response 401 M Street, S.W.

Washington, D.C. 20460 S. NAME AND ADDRESS OF OTHER ORGANIZATION Department of Health & Human Services (HHS)

Hubert Horatio Humphrey Building 2nd and Independence Avenues, S.W.

Washington, D.C. 20201;

4. PROJECT TITLE

This agreement provides \$971,118 to the Agency for Toxic Substances and Disease Registry (ATSDR) to cover obligations incurred for a study of residents of the Greater New Bedford, Massachusetts community to determine the extent of human exposure to poly-chlorinated biphenyls (PCB) from environmental contamination, contaminated aquatic local food supply, and occupational contact. A summary of the study is included as Attachment A.

Poly-chlorinated biphenyls (PCB) Health Study, Greater New Bedford

Estimated budget figures are included as Attachment B.

2 7 JUL 1984

U.S. V. AVX Original Litigation Document

S. SPECIAL PROVISIONS

This agreement may be terminated by either Agency upon 30 days advance written notice.

1. The Agency for Toxic Substances and Disease Registry will, in a timely manner, share and consult with EPA concerning all data obtained and all proposed recommendations/ conclusions which are based on health activities taken under terms of this agreement. Data will be shared with the Massachusetts Health Research Institute, Incorporated (on behalf of the Massachussets Department of Public Health) who are working with ATSDR under a cooperative agreement. Medical information about individuals obtained during their health evaluation will be provided to those individuals and/or their physicians at the request of the individuals. Interim and final reports, as well as recommended actions regarding health matters, will be issued by ATSDR only after review and consultation with EPA.

(See Attachment C)

. REPORTS

- An accounting by object class of funds obligated to date and during the current reporting period.
- A short narrative indicating progress made in the reporting period and the current status of health-related activities.
- Reports will be submitted to EPA 20 working days after the end of each quarter and upon completion of the project.

(See Attachment C)

Billie Perry	475-8100	Georgi Jones	TELEPHONE
ADDRESS	473-8100	ADDRESS	FTS 236-4100
Environmental Protection	n Agency (WH-548h)	Agency for Toxic Su	hetanoo
Office of Emergency and	•	& Disease Registry	
401 M Street, S.W.	Remedial Response	Disease Control (Ch	
Washington, D.C. 20460)	Atlanta, Georgia 30	· · · · · · · · · · · · · · · · · · ·
Z. EQUIPMENT-PROCUREMENT OF			•
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13. EQUIPMENT TO BE FURNISHED O	RACQUIRED		
As required within	approved budget.		.4
4. ESTIMATED COST			
a. TOTAL ESTIMATED PROJECT C	ost (\$ 971,118	b. AMOUNT TO BE FUNDED BY THIS AGREEMENT/AMENDMENT	\$ 971,118
EPA SHARE	971,118	EPA SHARE	\$ 971,118
OTHER AGENCY SHARE	s -0-	OTHER AGENCY SHARE	s -0-
*Unexpended amounts remaining 6. BILLING INSTRUCTIONS Request for payment will be made			
Environmental Protection	n Agency		
Financial Management Di	· · · · · · · · · · · · · · · · · · ·	3	
Room 214		•	
26 West St. Clair Stree			
Cincinnati, Ohio 45268			
and will cite the following accou		n en	TIEGNU.
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EPA Form 1410-1 (4-79)

DW75930893-01-0

Massachusetts Department of Public Health Greater New Bedford PCB Health Study

SUMMARY

The study about to be undertaken cooperatively between the U.S. Centers for Disease Control and the Massachusetts Department of Public Health will study the health effects of persons that reside in the Greater New Bedford, Massachusetts community who are at risk of exposure to poly-chlorinated biphenyls (PCBs) from environmental contamination, contaminated aquatic local food supply, and occupational contact.

The study will be conducted in two phases. Phase I will involve recruitment of residents of the community. These 1400 people will be randomly selected from census lists throughout the Greater New Bedford area and blood samples will be taken. The Phase I study will also collect data to determine the extent of PCB contamination in the population, route(s) of exposure, confounding exposure to chlorinated hydrocarbons and heavy metals, and blood pressure and will include limited collection of certain demographic information.

Phase II of this study will be a case-controlled study comprising two groups of approximately 150. The majority of these people will come from the results of the Phase I study. One set of these 150 individuals will have PCB blood levels above 30 ppb which we will refer to as the exposed group. The second group of 150 people will consist of 150 people with PCB blood levels lower than 10 ppb. These two groups will be matched for age, sex and ethinicity.

The Phase II study will be much more involved and will test several specific hypotheses concerning PCB health effects including biochemical measurements which will address several known and suspect PCB health effects. These will include tests of liver enzyme induction, alteration of lipid metabolism, depressed immune function and neurotoxicity.

It is anticipated that this program will continue for up to three years. The first year will include recruitment and training of staff, a pre-test period to verify forms, procedures and laboratory quality control, followed by Phase I examination, questionnaires, laboratory analyses and data entry. The latter part of the first year will include preliminary statistical analysis of Phase I data and detailed planning and preparation for Phase 2. Phase 2 pretesting and initial examinations are projected to begin at thirteen to fourteen months into the study (possibly later if a sufficient number of individuals with elevated PCB levels are not identified during Phase I and must be recruited from individuals at higher risk). Detailed statistical analysis and final report writing will commence at approximately twenty—one months into the study and are anticipated to continue through the third year.

DW75930893-01-0

Massachusetts Department of Public Health Greater New Bedford PCB Study

Combined CDC and MDPH Budgets

		Phase I	Phase II	Total
Α.	CDC Costs	62,848.94	61,570.12	\$ 124,419.06
В.	MDPH Costs	360,523.00	445,857.00	806,380.00
с.	CDC Indirect Costs For MDPH Budget (5% of B)	18,026.15	22,292.85	40,319.00
	Total costs			\$971,118.06

Continuation Sheet - Attachment C

8. Special Provisions

- 2. Reimbursements specified herein are contingent upon receipt, acceptance and approval by EPA of the quarterly status reports required by this interagency agreement.
- 3. ATSDR will retain detailed and accurate records for all costs for which reimbursement is requested under this agreement. Such documentation may be required by EPA from time to time to support cost recovery actions. Additionally, documentation must be available for audit or verification on request by the Inspector General.

9. Reports

In addition to the quarterly status reports, ATSDR will provide EPA documents/recommendations described in the Scope of Work.

All reports shall be submitted to:

William N. Hedeman, Jr., Director Office of Emergency & Remedial Response (WH-548) Office of the Comptroller (PM-225) Environmental Protection Agency Washington, D.C. 20460

Morgan Kinghorn, Comptroller Environmental Protection Agency Washington, D.C. 20460



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION I

J. F. KENNEDY FEDERAL BUILDING, BOSTON, MASSACHUSETTS 02203

U.S. V. AVX Original Litigation Document

RECEIVED

AUG 1 7 1984

REGION L OFFICE OF REGIONAL COUNSEL

The following was submitted to EPA by the Massachusetts Department of Public Health. These remarks are in response to public comments and questions raised as a result of a public meeting EPA held June 18, 1984 in Fairhaven, MA. A response from the Massachusetts Executive Office of Environmental Affairs will be mailed separately.

The Greater New Bedford Health Study is planned to be carried out in two phases. The first phase will select a random sample of adults living in New Bedford, Fairhaven, Dartmouth and Achushnet for several tests. These are:

- questionnaire about possible dietary or occupational exposures to PCB, past and current medical conditions, and residential history.
- serum PCB level.
- blood pressure, height and weight.

The purposes of this first phase are to describe the serum PCB levels in the general population of the area, and to identify individuals with high and low levels for study in Phase II.

Phase II will compare 150 persons with high levels of PCB to 150 persons with low levels of PCB for clinical findings, detailed laboratory testing, neurobehavioral findings, and a number of immunological markers. Proceeding to Phase II is dependent upon finding a sufficient number of persons with high levels of PCB from Phase I.

As to the report submitted by the Clean Water Action Project, the Department offers the following comments:

la) "identify diseases through the health study which might be detected and treated early if medical care providers are alerted to the effects of PCB..." As noted above this will be done in Phase II. Phase II can not be done until Phase I is accomplished.

A question was raised about health hazards of swimming in waters with high bacterial count. High bacterial counts can increase the risk of skin infections and of gastrointestinal disorders. Eye irritation and ear infections have also been reported in the public health literature.

The paper from the Environmental Defense Fund is useful. The Department also did a comprehensive review of the literature on the health effects of PCB. Many of the references in this paper are also cited in the bibliography contained in the proposal (pages 41-43).

For further clarifiction of health issues, contact:

Dr.David Gute Principal Investigator, New Bedford Health Study 150 Tremont Street Boston, MA 02111



The Commonwealth of Massachusetts Lepartment of Public Health 600 Washington Street Boston 02111

March 23, 1982

U.S. A. A.V. Original Lingation Document THE NEW BEDFORD PCB STUDY - PRELIMINARY FINDINGS

Last November, in cooperation with the New Bedford Health Gepartment, the Department of Public Health enlisted volunteers for a pilot study of the health effects of exposure to polychlorinated biphenyls. (PCB's).

PCB's are the chlorinated derivatives of a class of aromatic organic compounds called biphenyls. PCB's used in commercial products are colorless, odorless liquids containing mixtures of chlorobiphenyls. The chlorine content generally ranges up to 68 percent. PCB's, because of their thermal and chemical stability and low electrical conductivity found use in a number of applications as coolant insulation fluids in electrical transformers and capacitors, plasticizers in paints and plastics, and as a component of carbonless paper. Unfortunately, the same characteristics which make PCB's commercially useful are precisely those which lead to environmental accumulation in the food chain with concomitant adverse implications for public health and the environment.

The findings of this study must be interpreted cautiously for several reasons. Since the persons studied were volunteers, many of whom had known exposure to PCB's, no conclusions as to the PCB levels in the general population of New Bedford can be made. This question could be answered only by studying a

random sample of New Bedford residents. The number of subjects studied was only 51 so that it is difficult to control for confounding variables such as age or weight.

The group studied completed a health questionaire, including history of occupational exposure and of eating seafood taken from the Acushnet River. Each participant received a brief physical examination and gave blood and urine for laboratory enumerations. Analyses of the blood for PCB levels were performed by the Centers for Disease Control.

The PCB serum levels are summarized in Table 1. Because there were three persons with levels greater than 100 ppb, the median is a more accurate summary statistic than the mean. PCB levels >30 ppb were found in 16 persons. The highest levels were among those with long term occupational exposure. Nine of the 16 above 30 ppb had received occupational exposure. (Table 2). The remainder had frequently eaten fish or eels caught in the Acushnet River. (Table 3). It has been reported that New Bedford sewage contains PCB's. The wastewater treatment plant workers did not have elevated PCB levels. (Table 2).

The health data are difficult to interpret because of the small number of people studied. There was a weak association between PCB levels and blood pressure in persons less than 45 years, but some or all of this may be due to age, since older persons had higher PCB levels. (Table 4).

There was no correlation between PCB level and liver size or level of serum glutamic - oxaloacetic transaminase (SGOT), a non-specific liver function test.

There was a positive correlation between PCB levels and triglycerides, a finding which has been observed in other studies. Ten persons reported acne but none specified chloracne.

In summary, the highest PCB levels were found in occupationally exposed persons, there was no evidence of a relationship between PCB and liver disease,

a slight PCB level association with hypertension, and no greater than expected numbers of chronic conditions.

Since there is no therapy to reduce serum PCB levels, the Department of Public Health recommends that New Bedford residents abstain from eating seafood taken from the Acushnet River. There has been no occupational exposure to PCB's since 1977, when all use of PCB's in New Bedford ceased.

TABLE 1

SUMMARY OF PCB RESULTS

	MALES	<u>FEMALES</u>	ALL SUBJECTS
Number	39	12	51
Average Level (ppb)	41.7	13.5	36.2
Median Level (ppb)	1 7	9 '	15
Range (ppb)	2-343	4-64	2-343
N (%) ≥30 ppb N (%) ≥190 ppb	13 (3 3 %) 3 (3 %)	3 (25%) 9 (0%)	16 (31%) 3 (6%)

TABLE 2

SUMMARY OF PCB LEVELS AMONG SPECIFIC OCCUPATIONAL GROUPS

•	ELECTRICAL CAPACITOR MANUFACTURING	NEW BEDFORD WASTE WATER TREATMENT PLANT
Number	Э	10
Average Level (ppb)	126	13
Median Level (ppb)	õõ	10
N (%) 230 ppb Average Length (years)	9 (100%)	. 1* (10%)
of employment (range)	22 (5-38)	5 [120]

^{*}Worked both capacitor manufacturing plant and waste water treatment plant.

TABLE 3

SUMMARY OF PCB LEVELS AMONG THOSE REPORTING EVER/NEVER EATING SEAFOOD FROM THE ACUSHNET RIVER (EXCLUDING THOSE WITH LONG-TERM OCCUPATIONAL EXPOSURE)

	REPORTED EATING ACUSHNET RIVER SEAFOOD	REPORTED NEVER EATING ACUSHNET RIVER SEAFOOD
Number*	26	14
Average PCB Level (ppb)	21	12
Median PCB Level (ppb)	15	10.5
Range (ppb)	6-68	2-32
$N (\%) \ge 30 ppb$	6 (23%)	1 (7%)
$N (\%) \ge 15 ppb$	14 (54%)	4 (25%)

^{*2} persons did not respond to the question. Both had PCB levels of 6 ppb.

TABLE 3 · CANDIDATE DETERMINANTS OF SERUM PCB LEVELS

VARIABLE	Measure	Code	VARTABLE	MEASURE	Code
PCB Exposure	Exposure category Air levels	0 = Low 1 = MEDTUM 2 = HIGH	PLANT LOCATION		0 - FORT EDWARD 1 - HUDSON FALLS
SERUM LIPIDS	• TRIGLYCERIDES		DISEASE STATUS		0 - No DISEASE
	 FREE AND ESTERIF. CHOLESTEROL 	1.5 x TOTAL CLINI- CAL CHOLESTEROL	•		l = INTERCURRENT DISEASE DIABETES, ALCO-
	* TOTAL NEUTRAL LIPIDS	Tr: + 1.5 CHOL			HOLISM, ETC. (14 CASES)
SERUM PROTEINS	* ALBUMIN * GLOBULIN	CLINICAL VALUES	MIXED FUNCTION OXIDASE ACTIVITY		
TIME	SERVICE TIME AGE	PCB'S UUE	* SMOKING	 SMOKING CODE DAY YRS. SMOKED PACK-YRS 	0 = NON-SMOKERS 1 = X-SMOKERS 2 = SMOKERS
Sex		1 * MALE 2 * FEMALE	 ALCOHOL CONSUMPTION 		1 = NONE, RARE OR OCCAS.
SIZE OF FAT DEPOTS	* BODY FAT	HUME ONEYE'S			2 = WEEKLY 3 = DAILY
BODY HYDRATION	 Urinary specific GRAVITY 	LIINICAL. VALUE	* Liver Enzyme Activity	Total bilirubinDirect bilirubin	WALVES
Fasting/non-fasting Sample (1976)		1 = non-fasting 0 = Fasting	.* .	• SGOT	
HOURLY SALARIED		0 = BALARIES 1 = INUKLY		• GGTP	
JOB STATUS		U = Working 1 = Retired/ Separated	• Medications	•	

TABLE 4

RELATIONSHIP BETWEEN POB LEVELS AND HYPERTENSION

<45 Years of Age

HYPERTENSION CATEGORIES

•	MORMAL	BORDERLINE	DEFINITE	ELL SUBJECTS
				4
Number	27	₩ *		26
Average PCB Level		္ခ်စ္	30	<u>16</u>
Median PCB Level	<u> 9</u>	12	13	10
N (%) ≥30 ppb	0 (0%)	1 (25%)	<u> </u>	3 (11%)

>45 Years of Age

	NORMAL	BORDERLINE	DEFINITE	ALL SUBUECTS
Number Average PCB Level Median PCB Level	9 78 42	10 52 16	5 41 ◆ 43	24 60 32
N (%) ≥30 ppb	6 (67%)	3 (30%)	4 (80%)	13 (54%)

NORMAL - Systolic <140 mm, Diastolic <90 mm

BORDERLINE - Systolic 140-159 mm or Diastolic 90-94 mm

DEFINITE - Systolic ≥160 mm or Diastolic ≥95 mm



740 Belleville Ave. New Bedford, MA 02745 -Tel. (617) 994-9661 TELEX/TWX 710-344-6985

July 12, 1982

Mr. Richard F. Delaney Director Massachusetts Coastal Zone Management 100 Cambridge Street Boston, MA 02202

Dear Mr. Delaney:

*PCB Pollution In The New Bedford, Massachusetts Area: A Status Report" published by Grant Weaver of your office in June of this year, is a substantial work. He has covered the subject thoroughly. Unfortunately, the overall impression left to the reader by his report is that PCB is a very dangerous chemical, when in fact, whatever danger there is, is not well understood. This is not to say that the concern for the effects of PCB is not well placed but, his study seems to be based on the premise that PCB is inherently very toxic, and starting with this "fact" he proceeds to "prove" the presumption.

Several facts are indeed clear. First, PCB is indeed prevalent worldwide. Secondly, several of the 210 different types of PCB biodegrade very slowly. Third, PCB exists in very high concentrations in the Acushnet River, New Bedford Harbor, in the soil around Aerovox and Cornell-Dubilier, in the New Bedford landfill and perhaps in a number of other locations around the New Bedford area. But if one thing that is not well understood, it is the nature of the toxicity of this chemical. Many of the references that Mr. Weaver had used were published 6 to 8 years ago, and since then have been superseded by a number of far more sophisticated studies. Four that he might have used, and did not, are these:

- *Mortality and Industrial Hygiene Study of Workers Exposed to Polychlorinated Biphenyls", by David P. Brown, NIOSH April 1981.
- "Human Health Effects of Electrical-Grade PCB's", General Electric, August 1981.
- "Summary of the Health Effects of PCB's", November 1981, prepared for the Chemical Manufacturers Association by Ecology and Environment Incorporated of Buffalo, New York.

Mr. Richard F. Delaney Page 2 July 12, 1982

4. "The Potential Health Effects in Humans from Exposure to Polychlorinated Biphenyls (PCB's) and Related Impurities", January 1982 by Drill, Friess, Hays, Loomis and Shaffer, Inc., Consultants in Toxicology.

A review of these studies will indicate that the health effects attributable even to long term exposures to PCB's are minimal. Chloracne and dermatitis, which are both reversable, are found only on relatively rare occasions. Changes in skin pigmentation and retarded growth, also relatively rare, have also been shown to be temporary afflictions. Some forms of PCB have been found occasionally to accumulate in, and enlarge the human liver, but with no apparent adverse health effects, (similar to the effects of an enlarged heart on long distance runners). Certainly, the contention that PCB is carcinogenic is unproven. Further studies are and will be conducted on the long term effects of PCB's on human beings. In this vein, it might be of interest that the NIOSH studies referenced above on employees at Aerovox and G.E. are being continued.

Most importantly, insufficient emphasis in Mr. Weaver's report was given to the highly toxic nature of polychlorinated diebenzo-furans and polychlorinated quartelphenyls. Where human beings have become seriously ill, they have become so after exposure to these two by products. This was particularly true in the 1968 incident at Yusho, Japan.

There are a number of other issues that the Weaver report deals with incorrectly and these points are itemized in the attached outline.

Grant Weaver deals with most of the facets of this very complex problem, but some of his conclusions and the overall impression that he leaves the reader with concerning the overall toxic nature of PCB, are erroneous. We would hope that, in the future, Mr. Weaver using the four studies mentioned above and other responsible ones that will eventually come to light, will publish an addendum or supplement to his report that will correct these misconceptions.

Norman Butterworth

Norman Butterworth

Hanager Environmental Control

Sound I Blobardesa

Stuart L. Richardson Vice President Business Development

SLR/ke

Attachments

PCB POLLUTION IN THE NEW BEDFORD, MASSACHUSETTS AREA: A STATUS REPORT

The following errors were noted in the above report in the section entitled "Aerovox Incorporated", page 29.

- Page 29 second paragraph Aerovox actually used PCB's until October, 1978.
- 2. Page 30 Aerovox and Acushnet Capacitors plant schematic is badly in error. This print shows Acushnet Capacitors as a separate building, not having any discharge to the Acushnet River. Actually, there is only one building and Acushnet Capacitors (Acu-Cap) rents approximately 42,000 square feet on the second floor from Aerovox, Incorporated. In addition, the south trough discharge is essentially generated by Acu-Cap and they have a NPDES permit application which acknowledges that this trough discharge is their responsibility. We are enclosing an outline print showing the actual plant outline and that portion of the building which Acu-Cap occupies.
- 3. Page 31 top of the page
 The Aerovox NPDES discharge permit has not expired. There
 was a brief period of time between June 20, 1980 and August 25,
 1980 when we did not have an approved written extension of
 the November 25, 1975 permit (as modified on December 30,
 1976). This was due to the fact that we had not been notified
 by EPA, as we had believed we would be. We are enclosing
 copies of an EPA written extension dated August 25, 1980
 and of the current status as of April 29, 1981.
- 4. Page 31 third paragraph
 The report indicates all EPA and DEQE soil sampling on Aerovox property has documented the presence of high levels of PCB's.
 The Versar inspection of June 18, 1981 (for the EPA) included, at least one, soil analyzation which was less than the approved PCB level of 50 PPM.
- 5. Page 31 third paragraph
 "Seaward of the fence, sediment sampling revealed levels of
 680 to 190,000 PPM". Recently completed Coast Guard river
 mud sampling analytical results in, and close to, the back
 of the plant showed levels as low as 190 PPM on the surface
 and a 20 PPM (approximately 2' deep sample) from a point
 approximately 40' east of the plant property.

- Introduction Page 2 paragraph six
 It was not until 1972 that Aerovox went to AROCLOR 1016, and the Company continued to use PCB until October, 1978.
- Page 20 second paragraph, last sentence "PCB's are prohibited in any discharge from any electrical capacitor manufacturer". The Aerovox permit allows for a 10 PPB discharge to the river and as noted on page 33, the Cornell-Dubilier permit allows a similar limited discharge of PCB's to Buzzards Bay.
- 3. Page 24 paragraph six This paragraph references Table 4 which presents data on the fin fish results. While this table indicates some fairly high levels of PCB contamination, the latest results from the Department of Marine Fisheries shows a high of 3.2 parts per million on 9 samples taken from area 3.
- Page 43 paragraph six This paragraph states "Sediments taken from the New Bedford harbor any time during the last 50 years probably contain PCB's. Since neither Cornell-Dubilier or Aerovox were doing business in New Bedford 50 years ago, one might ask where PCB's in the harbor sediment would have come from in the early 1930's.
- Chronology Page 46 1977 "Aerovox develops..." The correct amount shown in the last line of that paragraph is 0.13 pounds, not 13 pounds. Purthermore, DEQE did not specifically disallow the practice, but since Aerovox found that a substitute for PCB would be commercially available within a short period after that time and the cost of implementing the process would be rather high, Aerovox decided not to pursue the issue any further.
- 1980 "Aerovox's waste water discharge permit expires." As indicated in an earlier segment of this analysis, the discharge permit has not expired.

XERO05

1. Septe